We claim:

1. A method of treating diabetes mellitus in a patient in need thereof, said method comprising:

(a) supplying a predetermined amount of powdered insulin to a hand held device, said predetermined amount being in excess of that amount required, in the bloodstream of said patient, to produce or maintain an acceptable serum glucose level in said patient;

(b) contacting said insulin with a compressed gas to form a cloud in said hand held device, said cloud comprising a repeatable amount of insulin, said repeatable amount being in excess of that amount required, in the bloodstream of said patient, to produce or maintain an acceptable serum glucose level in said patient, said cloud comprising insulin particles in the range between 0.25 and 6 microns; and

(c) inhaling said cloud at an inspiratory flow rate and volume adapted to deliver a portion of said cloud to the lungs of said patient, wherein a controlled and reproducible amount of said insulin from the cloud is absorbed in the bloodstream of said patient to produce or maintain an acceptable serum glucose level;

wherein step c is repeated during a dosing event and wherein for each repetition of step c insulin administration to the patient begins at substantially the same inspiratory flow rate and inspiratory volume.

2. A method of treating diabetes mellitus in a patient in need thereof, said method comprising:

(a) supplying a predetermined amount of powdered insulin to a hand held device, said predetermined amount being in excess of that amount required, in the bloodstream of said patient, to produce or maintain an acceptable serum glucose level in said patient;

(b) contacting said insulin with a compressed gas to form a cloud in said hand held device, said cloud comprising a repeatable and controlled amount of insulin, said repeatable and controlled amount being in excess of that amount required, in the bloodstream of said patient, to produce or

maintain an acceptable serum glucose level in said patient, said cloud comprised of insulin particles larger than 7 microns and smaller than 12 microns; and

(c) inhaling said cloud at an inspiratory flow rate and volume adapted to deliver a portion of said cloud to the lungs of said patient, wherein a predictable and controlled quantity of insulin from said cloud is absorbed by the patient via the patient's lungs and results in the patient maintaining an acceptable serum glucose level following administration of the insulin.

3. A method of treating diabetes mellitus in a patient in need thereof, said method comprising:

(a) mechanically supplying a predetermined amount of dry insulin powder to a given area of a hand held device, said predetermined amount being in excess of that amount required, in the bloodstream of said patient, to produce or maintain an acceptable serum glucose level in said patient;

(b) aerosolizing said insulin with a compressed gas, having a pressure less than 400 psi, to form a cloud in said hand held device, said cloud comprising a repeatable and controlled amount of insulin and further comprising particles having a size of less than 12 microns, said repeatable and controlled amount being in excess of that amount required, in the bloodstream of said patient, to produce or maintain an acceptable serum glucose level in said patient; and

(c) inhaling said cloud at an inspiratory flow rate and volume adapted to deliver controlled dose of insulin from a portion of said cloud to the lungs of said patient, wherein an amount of insulin absorbed by said patient is sufficiently predictable to produce or maintain a serum glucose level in said patient within a predetermined acceptable range.

4. A method of treating diabetes mellitus in a patient in need thereof, said method comprising:

(a) supplying a predetermined amount of insulin formulation comprising dry powder to a hand held device, said predetermined amount being in excess of that amount required, in the bloodstream of said patient, to produce or maintain an acceptable serum glucose level in said patient;

(b) contacting said insulin with a compressed gas having a pressure of less than 400 psi to

form a cloud in said hand held device, said cloud comprising a repeatable and controlled amount of insulin, said repeatable and controlled amount being in excess of that amount required, in the bloodstream of said patient, to produce or maintain an acceptable serum glucose level in said patient; and

(c) inhaling said cloud at an inspiratory flow rate and volume adapted to deliver to the patient for absorbtion a predictable and controlled dose from a portion of said cloud wherein the controlled and predictable dose is effective, in the bloodstream of said patient, to produce or maintain an acceptable serum glucose level;

(d) wherein the cloud is created prior to inhaling from the device.

5. A method of treating diabetes mellitus in a patient in need thereof, said method comprising:

(a) mechanically supplying a predetermined amount of insulin in the form of a dry powder to a given area of a hand held device, said predetermined amount being in excess of that amount required, in the bloodstream of said patient, to produce or maintain an acceptable serum glucose level in said patient;

(b) aerosolizing said insulin with a compressed gas to form a cloud in said hand held device, said cloud comprising a repeatable and controlled amount of insulin, said repeatable and controlled amount being in excess of that amount required, in the bloodstream of said patient, to produce or maintain an acceptable serum glucose level in said patient; said cloud comprising particles having an average size and comprising particles within 20% of the average size; and

(c) inhaling said cloud at an inspiratory flow rate and volume adapted to deliver a portion of said cloud to the lungs of said patient, wherein a predictable amount of insulin is transmitted to the bloodstream of said patient, to produce or maintain an acceptable serum glucose level.

6. A method of treating diabetes mellitus in a patient in need thereof, said method comprising:

(a) supplying a predetermined amount of insulin in the form of a dry powder to a hand held

device, said predetermined amount being 2 to 10 times that amount required, in the bloodstream of said patient, to produce or maintain an acceptable serum glucose level in the blood of said patient;

(b) contacting said insulin with a compressed gas to form a dry cloud in said hand held device, said cloud comprising a repeatable and controlled amount of insulin, said repeatable and controlled amount being 2 to 10 times that amount required, in the bloodstream of said patient, to produce or maintain an acceptable serum glucose level in the blood of said patient, wherein said cloud comprises particles having an average size and further comprises particle within 20% of the average size and wherein the cloud is further comprised of particles in the range between 7 and 12 microns; and

(c) inhaling said cloud at an inspiratory flow rate and volume adapted to deliver a portion of said cloud to the lungs of said patient, wherein the amount of insulin in said cloud is proportional to a desired dose of insulin that the patient will absorb upon inhalation so that a predictable quantity of insulin will be absorbed with sufficient precision to result in the patient achieving or maintaining an acceptable serum glucose level.

7. A method of treating diabetes mellitus in a patient in need thereof, said method comprising:

(a) mechanically supplying a predetermined amount of insulin in the form of a dry powder to a given area of a hand held device, said predetermined amount being 2 to 10 times that amount required, in the bloodstream of said patient, to produce or maintain an acceptable serum glucose level in said patient;

(b) aerosolizing said insulin with a compressed gas to form a dry cloud in said hand held device, said cloud comprising a repeatable and controlled amount of insulin, said repeatable and controlled amount being 2 to 10 times that amount required, in the bloodstream of said patient, to produce or maintain an acceptable serum glucose level in the blood of said patient, said cloud comprising particles of insulin in the range between 0.5 and 6 microns; and

(c) inhaling said cloud at an inspiratory flow rate and volume adapted to deliver a portion of said cloud to the lungs of said patient so that the patient will absorb into its blood stream a predictable controlled dose of insulin that results in an acceptable serum glucose level.

8. A method of treating diabetes mellitus in a patient in need thereof, said method comprising:

(a) supplying a predetermined amount of insulin in the form of a dry powder to a hand held device, said predetermined amount being 2 to 10 times that amount required, in the bloodstream of said patient, to produce or maintain an acceptable serum glucose level in said patient;

(b) contacting said insulin with a compressed gas to form a dry cloud in said hand held device, said cloud comprising a repeatable and controlled amount of insulin, said repeatable and controlled amount being 2 to 10 times that amount required, in the bloodstream of said patient, to produce or maintain an acceptable serum glucose level in the blood of said patient; and

(c) inhaling said cloud at an inspiratory flow rate and volume adapted to deliver a portion of said cloud to the lungs of said patient, wherein ito 30 units of insulin are absorbed into the bloodstream of said patient.

9. A method of treating diabetes mellitus in a patient in need thereof, said method comprising:

(a) mechanically supplying a predetermined amount of insulin in the form of a dry powder to a given area of a hand held device, said predetermined amount being 2 to 10 times that amount required, in the bloodstream of said patient, to produce or maintain an acceptable serum glucose level in said patient;

(b) aerosolizing said insulin with a compressed gas to form a dry cloud in said hand held device, said cloud comprising a repeatable and controlled amount of insulin, said repeatable and controlled amount being 2 to 10 times that amount required, in the bloodstream of said patient, to produce or maintain an acceptable serum glucose level in the blood of said patient, said cloud comprising particles of insulin in the range from 0.5 and 12 microns; and

(c) inhaling said cloud at an inspiratory flow rate and volume adapted to deliver a portion of said insulin cloud to the lungs of said patient, wherein 1 to 30 units of insulin are absorbed into the

bloodstream of said patient.

10. A method of treating diabetes mellitus in a patient in need thereof, said method comprising:

(a) supplying a predetermined amount of insulin in the form of a dry powder to a hand held device, said predetermined amount being 2 to 300 units of insulin;

(b) contacting said insulin with a compressed gas to form a dry cloud in said hand held device, said cloud comprising a repeatable and controlled amount of insulin, said repeatable and controlled amount being 2 to 300 units of insulin, said cloud comprising insulin particles in the range that is greater than 7 microns and less than 12 microns; and

(c) inhaling said cloud at an inspiratory flow rate and volume adapted to deliver a portion of said cloud to the lungs of said patient; wherein 1 to 30 units of insulin are repeatably absorbed into the bloodstream of said patient.

11. A method of treating diabetes mellitus in a patient in need thereof, said method comprising:

(a) mechanically supplying a predetermined amount of insulin in the form of a dry powder to a given area of a hand held device, said predetermined amount being 2 to 300 units of insulin;

(b) aerosolizing said insulin with a compressed gas having a pressure less than 400 psi to form a dry cloud in said hand held device, said cloud comprising a repeatable and controlled amount of insulin, said repeatable and controlled amount being 2 to 300 units of insulin; said cloud having particles with an average diameter and wherein 80% of the particles are within 20% of the average diameter; and

(c) inhaling said cloud at an inspiratory flow rate and volume adapted to deliver a portion of said cloud to the lungs of said patient; wherein 1 to 30 units of insulin are repeatably absorbed into the bloodstream of said patient.

12. A method of treating diabetes mellitus in a patient in need thereof, said method comprising:

(a) determining the amount of insulin required, in the bloodstream of said patient, to produce or maintain an acceptable serum glucose level;

(b) aerosolizing, in a hand held device, a predetermined amount of insulin in excess of said required amount of insulin with a compressed gas to form a cloud in said hand held device, said cloud comprising a repeatable amount of insulin in excess of said required amount of insulin, wherein said cloud is comprised of particles less than 12 microns in size; and

(c) inhaling said cloud at an inspiratory flow rate and volume adapted to deliver a portion of said insulin cloud to the lungs of said patient, wherein said required amount of insulin is absorbed into the bloodstream of said patient.

13. A method of treating diabetes mellitus in a patient in need thereof, said method comprising:

(a) determining the amount of insulin required, in the bloodstream of said patient, to produce or maintain an acceptable blood glucose level;

(b) aerosolizing, in a hand held device, a predetermined amount of insulin in excess of said required amount of insulin with a compressed gas to form a cloud in said hand held device, said cloud comprising a repeatable and controlled amount of insulin in excess of said required amount of insulin and comprised of particles less than 12 microns; and

(c) inhaling said cloud at an inspiratory flow rate and volume adapted to deliver a portion of said cloud to the lungs of said patient, wherein said required amount of insulin is absorbed into the bloodstream of said patient, wherein the inhaling is repeated a plurality of times and wherein for each repetition the insulin administration begins at substantially the same inspiratory flow rate and volume.

14. A method of treating diabetes mellitus in a patient in need thereof, said method comprising:

(a) determining the amount of insulin required, in the bloodstream of said patient, to produce or maintain an acceptable serum glucose level;

(b) aerosolizing, in a hand held device, a predetermined amount of a dry powder form of insulin 2 to 10 times said required amount of insulin with a compressed gas to form a dry cloud in said hand held device, said cloud comprising a repeatable and controlled amount of insulin, said repeatable and controlled amount being 2 to 10 times said required amount of insulin; said cloud comprised of particles larger than 12 microns and

(c) inhaling said cloud at an inspiratory flow rate and volume adapted to deliver a portion of said cloud to the lungs of said patient, wherein said required amount of insulin is absorbed into the bloodstream of said patient.

15. A method of treating diabetes mellitus in a patient in need thereof, said method comprising:

(a) determining the amount of insulin required, in the bloodstream of said patient, to produce or maintain an acceptable serum glucose level, said required amount being 1-30 units;

(b) aerosolizing, in a hand held device, a predetermined amount of a dry powder comprising insulin, said predetermined amount being 2 to 10 times said required amount of insulin, with a compressed gas to form a dry cloud in said hand held device, said cloud comprising a repeatable and controlled amount of insulin, said repeatable and controlled amount being 2 to 10 times said required amount of insulin; and

(c) inhaling said cloud at an inspiratory flow rate and volume adapted to deliver a portion of said cloud to the lungs of said patient, wherein from 1 to 30 units of insulin are absorbed into the bloodstream of said patient.

16. A method of treating diabetes mellitus in a patient in need thereof, said method comprising:

(a) determining the amount of insulin required, in the bloodstream of said patient, to produce or maintain an acceptable serum glucose level, said required amount being from 1-30 units;

(b) aerosolizing, in said hand held device, a predetermined amount of insulin in the form of a

dry powder, said predetermined amount being from 2 to 300 units of insulin, with a compressed gas to form a dry cloud in said hand held device, said cloud comprising a repeatable and controlled amount of insulin, said repeatable and controlled amount being from 2 to 300 units of insulin; and

(c) inhaling said cloud at an inspiratory flow rate and volume adapted to deliver a portion of said insulin cloud to the lungs of said patient; wherein from 1 to 30 units of insulin are repeatably absorbed into the bloodstream of said patient and wherein the inspiratory volume and flow rate at the beginning of insulin administration are substantially equal in value.

17. A method of treating diabetes mellitus in a patient in need thereof, said method comprising:

(a) aerosolizing, in a hand held device, a first predetermined amount of insulin, which is in excess of the amount of insulin required, in the bloodstream of said patient, to produce or maintain an acceptable serum glucose level, with a compressed gas to form a first cloud in said hand held device, said first cloud comprising a first repeatable and controlled amount of insulin which is in excess of the amount of insulin required, in the bloodstream of said patient, to produce or maintain an acceptable serum glucose level;

(b) inhaling said first cloud at an inspiratory flow rate and volume adapted to deliver a portion of said first cloud to the lungs of said patient, wherein insulin is absorbed into the bloodstream of said patient; and

(c) repeating (a) and (b) with a second predetermined amount of insulin which is the same as or different from said first predetermined amount and is in excess of the amount of insulin required, in the bloodstream of said patient, to produce or maintain an acceptable serum glucose level and a second repeatable and controlled amount of insulin which is the same as or different from said first repeatable and controlled amount and is in excess of the amount of insulin required, in the bloodstream of said patient, to produce or maintain an acceptable serum glucose level.

18. A method of treating diabetes mellitus in a patient in need thereof, said method comprising:

(a) aerosolizing, in a hand held device, a first predetermined amount of insulin in the form of a dry powder with a compressed gas to form a first cloud in said hand held device, said first predetermined amount being an amount in excess of the amount of insulin required, in the bloodstream of said patient, to produce or maintain an acceptable serum glucose level, said first cloud comprising a first repeatable and controlled amount of insulin which is in excess of the amount of insulin required, in the bloodstream of said patient, to produce or maintain an acceptable serum glucose level;

(b) inhaling said first cloud at an inspiratory flow rate and volume adapted to deliver a portion of said first cloud to the lungs of said patient, wherein insulin is absorbed into the bloodstream of said patient; and

(c) repeating (a) and (b) with a second predetermined amount of insulin which is the same as or different from said first predetermined amount and is in excess of the amount of insulin required, in the bloodstream of said patient, to produce or maintain an acceptable serum glucose level and a second repeatable and controlled amount of insulin which is the same as or different from said first repeatable and controlled amount and is in excess of the amount of insulin required, in the bloodstream of said patient, to produce or maintain an acceptable serum glucose level.

19. A method of treating diabetes mellitus in a patient in need thereof, said method comprising:

(a) aerosolizing, in a hand held device, a first predetermined amount of insulin in the form of a dry powder, said first predetermined amount being 2 to 10 times that amount required, in the bloodstream of said patient, to produce or maintain an acceptable serum glucose level in said patient, with a compressed gas to form a first dry cloud in said hand held device, said first cloud comprising a first repeatable and controlled amount of insulin which is 2 to 10 times that amount required, in the bloodstream of said patient, to produce or maintain an acceptable serum glucose level in said patient;

(b) inhaling said first cloud at an inspiratory flow rate and volume adapted to deliver a portion of said first cloud to the lungs of said patient, wherein insulin is absorbed into the bloodstream of said patient;

(c) repeating (a) and (b) with a second predetermined amount of insulin which is the same as or different from said first predetermined amount and is in excess of the amount of insulin required, in the bloodstream of said patient, to produce or maintain an acceptable serum glucose level and a second repeatable and controlled amount of insulin which is the same as or different from said first repeatable and controlled amount and is in excess of the amount of insulin required, in the bloodstream of said patient, to produce or maintain an acceptable serum glucose level.

20. A method of treating diabetes mellitus in a patient in need thereof, said method comprising:

(a) aerosolizing, in a hand held device, a first predetermined amount of insulin in the form of a dry powder, said first predetermined amount being 2 to 10 times that amount required, in the bloodstream of said patient, to produce or maintain an acceptable serum glucose level in said patient, with a compressed gas to form a first dry cloud in said hand held device, said first cloud comprising a first repeatable and controlled amount of insulin which is 2 to 10 times that amount required, in the bloodstream of said patient, to produce or maintain an acceptable serum glucose level in said patient;

(b) inhaling said first cloud at an inspiratory flow rate and volume adapted to deliver a portion of said first cloud to the lungs of said patient, wherein 1 to 30 units of insulin are absorbed into the bloodstream of said patient;

(c) repeating (a) and (b) with a second predetermined amount of insulin which is the same as or different from said first predetermined amount and is 2 to 10 times that amount of insulin required, in the bloodstream of said patient, to produce or maintain an acceptable serum glucose level and a second repeatable and controlled amount of insulin which is the same as or different from said first repeatable and controlled amount and is 2 to 10 times that amount of insulin required, in the bloodstream of said patient, to produce or maintain an acceptable serum glucose level.

21. A method of treating diabetes mellitus in a patient in need thereof, said method comprising:

(a) aerosolizing, in a hand held device, a first predetermined amount of insulin in the form of

a dry powder, said first predetermined amount being 2 to 300 units of insulin, with a compressed gas to form a first dry cloud in said hand held device, said first cloud comprising a first repeatable and controlled amount of insulin being 2 to 300 units of insulin;

(b) inhaling said first cloud at an inspiratory flow rate and volume adapted to deliver a portion of said first cloud to the lungs of said patient; wherein from 1 to 30 units of insulin are repeatably absorbed into the bloodstream of said patient;

(c) repeating (a) and (b) with a second predetermined amount which is the same as or different from said first predetermined amount and is 2 to 300 units of insulin and a second repeatable and controlled amount which is the same as or different from said first repeatable and controlled amount and is 2 to 300 units of insulin.

22. A method of treating diabetes in a patient in need of treatment for diabetes, the method comprising:
    a. Determining a desired dose of insulin that, when absorbed by the patient's body will result in an acceptable serum glucose level;
    b. Aerosolizing in a handheld device a predetermined amount of dry powder insulin by creating a cloud within the device, the predetermined amount being in excess of the desired dose;
    c. Inhaling at least a portion of the cloud at an inspiratory volume and flow rate adapted to deliver into the blood stream of the patient via the lungs of the patient an amount of insulin that is substantially identical to the desired dose of insulin such that the patient's achieves the acceptable serum glucose level, wherein the amount of insulin inhaled in the cloud is greater than the desired dose.

23. The method of claim 22, wherein the inhalation in step c occurs over a plurality of inhalations.

24. The method of lowering the blood glucose level in a diabetic patient, the method comprising the steps of:
    a. determining a desired dose of insulin that, when absorbed by the patient will result in an acceptable serum glucose level;
    b. at a first dosing event:

i. administering the an aerosolized predetermined amount of dry powder insulin to the patient by first creating a cloud of insulin and air that contains an quantity of insulin in excess of the desired dose;

ii. inhaling at least a portion of the cloud, in one or more breaths, at an inspiratory volume and flow rate adapted to allow a quantity of insulin to be delivered to the patient's blood stream via the lungs that is substantially the same as the desired dose so that the patient achieves the acceptable serum glucose level;

c. at a second dosing event:

i. administering the an aerosolized predetermined amount of dry powder insulin to the patient by first creating a cloud of insulin and air that contains an quantity of insulin in excess of the desired dose;

ii. inhaling at least a portion of the cloud, in one or more breaths, at an inspiratory volume and flow rate adapted to allow a quantity of insulin to be delivered to the patient's blood stream via the lungs that is substantially the same as the desired dose so that the patient achieves the acceptable serum glucose level;

wherein the amount of insulin absorbed during the first dosing event and the second dosing event does not vary substantially;

25. The method of claim 24, wherein determining whether the dose delivered to the patients blood stream is substantially the same as the desired dose is determined by comparing whether the patient's serum blood glucose level is in an acceptable range.